

REMARKS

Claims 1-4, 6-8, 11-22 and 24-28 are pending in the present application and have been rejected. Claim 24 is amended herein.

Rejections Pursuant to 35 U.S.C. §103

In the Office Action, claims 1-4, 6, 15-17, 19-22, 24 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Zhao et al. (U.S. Pat. Pub. No. 2002/0079219 A1) in view of Ekström et al. (U.S. Patent No. 5,376,252). It is asserted in support of the instant rejection that although the device disclosed by Zhao et al. differs from the claimed device in that it does not comprise multi-tiered layers, nor do Zhao et al. disclose a layer made from insulating foil material or a transparent window for observing the sample fluid, Ekström et al. disclose a microfluidic device for processing fluid samples (i.e., separation, detection) (see Fig. 7A), the device comprising vertically alternating layers 2 and 3 such that a plurality of channels 4 defined by recesses/gaps in layer 3 are aligned on top of one another, and that the stacked configuration enables the formation of multi-storied structures and complex channel geometries for conducting reactions and analyses (see col. 8, lines 25-35). In light of the disclosure of Ekström et al., the Examiner asserted it would have been obvious to one of ordinary skill in the art to stack the layers of the microfluidic device disclosed by Zhao et al. to form multi-storied microfluidic channel networks, and that the multi-storied configuration would enable complex reactions and analyses.

Claims 7 and 8 are rejected under §103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Akridge et al. (U.S. Pat. No. 5,141,614). Claims 11-13, 25, 27 and 28 are rejected under §103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Oloman et al. (U.S. Pat. No. 4,118,305). Claim 14 is rejected under §103(a) as being unpatentable

over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Stapleton et al. (U.S. Pat. No. 5,922,604). And claim 18 is rejected under §103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Weigl et al. (U.S. Pat. Pub. No. 2001/0027745 A1).

Claim 1 of the present application recites a device for analyzing a biological liquid sample comprising a composite body of a plurality of layers of flat material defining at least one sample channel for transporting the sample liquid from an application site to a measuring site, wherein the plurality of layers of flat material comprise a plurality of transport layers arranged in a stack-like manner between support layers. The sides of the support layers that face the transport layers are coated with an electrode layer comprising an electrically conductive material. In addition, the support layers are displaced relative to one another in a step-like manner, such that the electrode layers comprise a connecting section extending beyond an adjacent transport layer.

Claim 24 is amended herein and recites a device for analyzing a biological liquid sample comprising a plurality of liquid sample channels for providing capillary flow of the liquid sample from an application site to a measuring site, wherein said channels are defined by plurality of alternating support layers and transport layers, wherein the transport layers each comprise two pieces of material having opposing edges which comprise side walls of the channels and the support layers comprise top and bottom walls of the channels, and wherein said support layers are displaced relative to one another in a step-like manner. Support for this amendment can be found in the claims as originally filed, e.g., claim 10, in para. [0016] of the specification, for instance, and in various figures. No new matter has been added.

As noted herein and in the Office Action, the device disclosed by Zhao et al. differs from the claimed device, *inter alia*, in that it does not comprise multi-tiered layers.

Ekström et al. disclose a microfluidic structure comprising first and second substantially planar form-stable base layers and an intermediate spacing layer of elastic material that is recessed to define a microcavity or channel system with at least one of the first and second base layers (see Abstract). The structure shown in Fig. 3 of the Ekström et al. patent, including the base layer 2 and the spacing layer 3 supported thereby, may be used to build up multi-storied structures as is schematically illustrated in Fig. 7A showing three superimposed spacing layer/base layer assemblies according to Fig. 7B. In such manner very complex channel geometries for reactions and analyses may be constructed. The channels of adjacent spacing layers 3 may be connected by bores in the respective base layers, the channel ends then being closed as in base layer 2a in Fig. 5. (see col. 8, lines 24-33). As noted in the Office Action, the device comprises vertically alternating layers 2 and 3 such that a plurality of channels 4 defined by recesses/gaps in layer 3 are aligned on top of one another.

This teaching however does not fulfill the deficiencies of Zhao et al., as Ekström et al. do not disclose any step-like sandwich structure, but rather an overlapping of the uniformly stacked base layers 2 (see, e.g., Fig. 7A). Zhao et al. and Ekström et al. cannot be relied upon in support of the instant rejection as the disclosures, either alone or in combination, do not teach all of the elements recited in claim 1 (a device for analyzing a biological liquid sample . . . wherein the plurality of layers of flat material comprise a plurality of transport layers arranged in a stack-like manner between support layers, the sides of the support layers that face the transport layers are coated with an electrode layer comprising an electrically conductive material, and the support layers are displaced relative to one another in a step-like manner, such that the electrode layers comprise a connecting section extending beyond an adjacent transport layer), nor claim 24 as amended herein, which also recites the support layers are displaced relative to one another in a step-like manner.

To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed

invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. In the Office Action, it is asserted that the arguments presented in the Amendment filed on 4 October 2007 were not persuasive because Ekström et al. demonstrate that it is possible to form multi-layered microfluidic devices that comprise electrodes, that Figs. 1, 2, 5 and 10 of Ekström et al. show embodiments of the invention comprising electrodes in the substrate layer, and that Fig. 7A shows that layers of substrates can be assembled to form a multi-tiered device. The Examiner concluded that based on the disclosure, there is motivation for stacking the layers of the Zhao et al. device to form a multi-layered device wherein each unit comprises a substrate 18, electrodes 28 and a cover 20 as shown in Fig. 2 of Zhao et al. Both this rationale and the disclosures of Zhao et al. and Ekström et al. however do not address all of the limitations recited in claims 1 and 24, more specifically, that the support layers of the device for analyzing a biological liquid sample are displaced relative to one another in a step-like manner and, with respect to claim 1, such that the electrode layers comprise a connecting section extending beyond an adjacent transport layer.

Contrary to the assertions made in the Office Action, Zhao et al. appear to disclose a device with a single transport layer, which transport layer is not arranged between support layers, as recited in claims 1 and 24 of the present application. In contrast to the present invention, in all examples, Zhao et al. propose to bond a single cover to a single substrate. Specifically, referring to Fig. 3C, a cover 94 is bonded to a substrate 92 by an adhesive 98 (see, para. [0090]). Although it is said that the adhesive acts as a spacer, this is distinguishable from the transport or support layers recited in claims 1 and 24 of the instant application. It is undisclosed and unclear how the channel 99 is formed in the adhesive 98 overlapping the electrode. It appears clear however that the channel 99 formed by the adhesive 98 is not intended for transporting the sample liquid. Indeed, Zhao et al. teach away from the present invention by reciting in para. [0091], for instance, that it is the substrate that has microchannels and wells. Zhao et al. is deficient in its teaching of the present invention and cannot be relied upon.

in support of the instant rejection. Ekström et al.'s teaching of uniformly stacked base layers devoid of any step-like arrangement do not fulfill these deficiencies.

In addition, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Zhao et al. disclose only one substrate 18 as a transport layer, with integrated electrodes 28 that have leads only on one side of the single layer substrate. While in this basic configuration a conventional connection like on a planar circuit board may be possible, the connection however fails in a stacked configuration where both sides of each support layer are connected. Zhao et al. propose patterning of ink to form the electrodes and especially the connecting section (see, para. [0010] and [0085]), but do not at all propose forming a connecting section by a step-like arrangement of support layers and electrode layers in a multi-layer stack. In addition, Ekström et al. do not disclose any electrodes in connection with the "multi story" structure, but rather focus on optical windows (see col. 9, lines 39-40).

For all of the reasons set forth herein, applicants submit that Zhao et al. cannot be relied upon in support of the instant rejection, and Ekström et al. do not fulfill the deficiencies of Zhao et al. Claims 2-4, 6-8, 11-22 and 25-28 contain all of the limitations of the base claim from which they depend. Applicants respectfully submit that the Examiner has not presented a *prima facie* case of obviousness and request that the rejections be withdrawn.

CONCLUSION

Applicants have filed a complete response to the outstanding Office Action and respectfully submit that, in view of the above amendments and remarks, the application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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